DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 8th, 2010 has been entered.

Claims 1 and 3-30 remain pending with claims 12-16 and 26-30 withdrawn from consideration as being directed to a non-elected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3-11, and 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the contents" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the other/others" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the terminally sterilized solution" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "said compartments" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 3-6, 8-9, 11 and 17-25 are rejected for the same reasons as applied to claim 1 above, since they depend from and include all of the limitations of independent claim 1.

Claim Objections

4. Claim 11 is objected to because of the following informalities: Line 1 of claim 11 fails to recite the claim from with it depends. Appropriate correction is required.

5. Claim 17 is objected to because of the following informalities: Claim 17 depends from canceled claim 2. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 3-11, and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonsson et al. (U.S. Patent No. 5,536,469) in view of Breborowicz et

al. (document titled "Replacement of Glucose with N-Acetylglucosamine in Peritoneal Dialysis Fluid").

Jonsson et al. discloses a sterile medical solution containing glucose or glucose-like compounds for peritoneal dialysis (see col. 1, lines 54-56). The content of the glucose-like compounds are preferably in the order of 40% by weight (see col. 1, lines 60-65). Jonsson et al. further discloses heat sterilization of the final solution (see col. 2, line 2) between a temperature of 110°C and 150°C (see col. 2, line 10), specifically 121°C (see col. 5, lines 1-5). Heat sterilization necessarily involves some degree of heat transfer provided by convection, conduction, and thermal radiation in the form of non- ionizing infra-red radiation, and therefore interpreted broadly heat sterilization meets the definition of radiation sterilization. Jonsson et al. also discloses the final solution optimized at a pH between 6.5 and 7.5, preferably about 7.0 (see col. 2, lines 55-56) and the solution mixed and diluted to 1.5% glucose content after sterilization (see col. 2, lines 57-61). Jonsson et al. further discloses the solution contains low levels of cytotoxic degradation products (see col. 4, lines 3-5). Jonsson et al. further discloses the solution in a bag system (see col. 4, lines 11-20) which is a container comprising at least one compartment.

However, Jonsson et al. does not specifically disclose a medical solution containing one or more acetylated or deacetylated amino sugars nor does Jonsson et al. specifically disclose the preparation of a final medical solution wherein the pH is 7.4.

Breborowicz et al. teaches that partial replacement of glucose with N-acetylglucosamine (NAG) in peritoneal dialysis fluid results in advantageous

preservation of the peritoneal membrane (see page 365, left column, paragraph 1). Breborowicz et al. also teaches supplementation of the dialysis fluid with hyaluronan, a human glucoseaminoglycan, results in the advantageous suppression of inflammatory reaction induced by peritoneal dialysis (see page 365, right column, paragraph 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Jonsson et al. in view of the teachings of Breborowicz et al.

One of ordinary skill in the art would be motivated to modify Jonsson et al. with the teachings of Breborowicz et al. because Breborowicz teaches that it is advantageous to partially replace glucose with N- acetylglucosamine (NAG), which is more biocompatible, giving a solution comprising both NAG molecules and the physiologically compatible constituents glucose molecules. The combination thus achieves the predictable result of improving the medical solution of Jonsson et al. based upon the teachings of Breborowicz et al.

Furthermore, one of ordinary skill in the art would be motivated to practice the invention of Jonsson et al. in view of Breborowicz et al. wherein the one or more acetylated or deactivated amino sugars is human glucoseaminoglycan because Breborowicz et al. teaches supplementation of the dialysis fluid with hyaluronan (a human glucoseaminoglycan) which results in the advantageous suppression of inflammatory reaction induced by peritoneal dialysis.

In addition, one of ordinary skill in the art would be motivated to optimize the final medical solution wherein the pH is 7.4 because Jonsson et al. teaches the final

peritoneal dialysis solution optimized at a pH between 6.5 and 7.5, and it is well known in the biological field that pH 7.4 is the common blood plasma pH and therefore an optimally biocompatible pH.

Response to Arguments

8. Applicant's arguments filed January 8, 2010 have been fully considered but they are not persuasive.

The Applicant first argues the following on pages 3-5:

"A. A melting point value for N-acetylglucosamine has no bearing on the thermochemical stability of N-acetylglucosamine in a solution with a pH of 2.5-3.5"

The Examiner respectfully disagrees. The melting point value of N-acetylglucosamine was not relied upon to teach that the thermochemical stability of N-acetylglucosamine in a solution with a pH of 2.5-3.5 or the stability of the solution at temperatures used for heat sterilization. The melting point temperature of N-acetylglucosamine was rather used to serve as guidance and also to suggest to one of ordinary skill in the art that there would be a "reasonable" expectation of success that the N-acetylglucosamine would be suitable for use in the low pH solution and heat sterilization process of Johnsson et al., in addition to the motivation disclosed by Breborowicz et al.

The Applicant further argues the following on pages 5-10:

"B. The Office has failed to make a prima facie case of obviousness because it has failed to show that one of ordinary skill in the art would have combined the references as proposed"

1. The prior art teaches away from the instant invention

Rovati et al. (U.S. Patent No. 3,697,652) ("Rovati) teach pharmaceutical preparations, including injectable aqueous solutions, that contain as the active ingredient one or more acetylated amino sugars, such as, for example, N-acetylglucosamine (NAG)…

This argument is not persuasive as "Rovarti" has not been relied upon in any rejection of claims 1, 3-11, and 17-25.

The Applicant further argues the fooling on pages 10-13:

"2. One of ordinary skill in the art had "no good reason" nor guidance to pursue the proposed combination of prior art references"

"One of ordinary skill in the art had no good reason nor guidance to pursue the proposed combination suggested by the Office for several reasons. First, Rovati teaches away from replacing glucose in Jonsson's method of preparing a medical solution with the NAG of Breborowicz. Jonsson uses a low pH during heat sterilization of its glucose-containing solution, preferably a pH of about 3.5, and then changes the pH of the solution to neutral, i.e. to a pH of about 7.0:"

The Examiner respectfully disagrees. First, Rovati has not been relied upon in the rejection of the claims under 35 U.S.C. 103(a). Therefore, the arguments regarding the "Rovarti" reference are not persuasive.

The Applicant further argues on page 11:

"Second, Breborowicz uses filtration, rather than heat, and a neutral pH, rather than a low pH, to sterilize its NAG-containing solution. Breborowicz at page S365, last full ¶ ("Fluids were sterilized by filtration and their pH was 7.05"). Furthermore, Breborowicz teaches that glucose and NAG are different compounds in the context of dialysis fluids, for example, causing different biological responses:"... "Thus, one of skill in the art reading Breborowicz would have had no good reason to conclude that NAG and glucose are interchangeable compounds in the medical solution according to Jonsson in the context of heat-sterilization."

The Examiner respectfully disagrees. Breborowicz has not been relied upon to teach how they sterilize their solution but rather that partially replacing glucosamine with N-Acetylglucosamine in medical solutions yields improvements in a peritoneal dialysis solution. Breborowicz teaches "partial" replacement of glucose with NAG and thus one of skill in the art would have good reason to conclude that glucose can be partially replaced with NAG in any know dialysis solution, including the solution of Jonsson.

The Applicant further argues the following on pages 11-12:

"Third, Jonsson discloses using a low pH during sterilization specifically for glucose, but not for any other chemical compound that may replace glucose in the medical solution:"

"One of skill in the art would have had no good reason to conclude that the low pH used by Jonsson during sterilization of a glucose-containing solution would be applicable to the sterilization of a solution containing any other chemical compound, such as NAG, particularly given the disclosure in Rovati advising against changing the pH of the solution."

The Examiner respectfully disagrees. Again, Rovati is not relied upon in the rejection of the claims. The teaching of Breborowicz that glucose is partially replaced by NAG in a peritoneal dialysis fluid for improved results is a sufficient teaching for partially replacing the glucose or glucose-like compounds in the invention of Jonsson. Johnsson discloses the use of glucose or glucose-like compounds (col. 1, lines 50-60) in the medical solution and therefore, Johnsson discloses the process is suitable for other compounds than just glucose. The teaching of glucose-like compounds in Johnsson provides the suggestion to try other glucose like compounds such as NAG disclosed by Breborowicz. Concerning the argument regarding the pH during sterilization, the process of Johnsson discloses the claimed pH range. Partially substituting the glucose with NAG as taught by Breborowicz does not change the fact that Johnsson requires the pH to be around 3.5 during sterilization.

Thus, it would have been obvious to partially replace the glucose in Johnsson with NAG as exemplified by Breborowicz and furthermore, it would have been obvious

to utilize the sterilization process disclosed by Johnsson on the medical solution containing NAG.

The Applicant further argues the following on page 13:

"3. There was no reasonable expectation of success in arriving at the claimed invention"

"One of ordinary skill in the art had no reasonable expectation of success in arriving at the claimed invention based on Jonsson and Breborowicz for the reasons presented in the amendment filed on July 13, 2009, and the additional arguments discussed in the previous sections,"

This argument is not persuasive for at least the reasons stated previously regarding the "reasonable expectation of success".

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Conley whose telephone number is 571-272-8414. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Sean E Conley/
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